

### **REMARKS**

Claims 11 and 14-25 were pending. Claim 11 was amended. Therefore, claims 11 and 14-25 will be pending upon entry of the instant amendment.

No new matter has been added. Support for the amendment to claim 11 can be found in the originally filed specification, for example, at least at page 26, lines 20-24.

Applicants gratefully acknowledge the withdrawal of the rejection of claims 11 and 14-20 under 35 U.S.C. § 112, first paragraph.

#### ***Rejection of Claims 11 and 14-18 under 35 U.S.C. § 102(b)***

Claims 11, and 14-18 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Mangeney *et al.* (*Cancer Research* 53, 5314-19, Nov. 1993).

Claims 11 and 14-18 are directed to a method for killing primary Gb<sub>3</sub> positive cancer cells from a patient *in vitro*, by obtaining the cells from the patient, and contacting the cells with a verotoxin.

Mangeney *et al.* describes the effects of verotoxin on various cell lines. According to the Examiner, Mangeney *et al.* “teaches the apoptosis of cancer cells following administration of verotoxin.” Mangeney *et al.* use cells obtained from a cell line, and not *primary* cells from a patient. Mangeney *et al.* fails to teach or suggest obtaining primary cells from a patient and treating the primary cells *in vitro* with verotoxin, as claimed by Applicants.

Therefore, Applicants request that this rejection of claims 11 and 14-18 under 35 U.S.C. § 102(b) be withdrawn.

#### ***Rejection of Claims 11 and 14-18 under 35 U.S.C. § 102 (b) or 35 U.S.C. § 103 (a)***

Claims 11, and 14-18 are rejected under 35 U.S.C. § 102 (b) as being anticipated by, or alternatively, under 35 U.S.C. § 103 (a) as being obvious over Mangeney *et al.* According to the Examiner, Mangeney *et al.* “one of the holotoxins was used and it would have been obvious for one of ordinary skill in the art at the time of the invention to substitute any of the known variants.”

As described above, Mangeney *et al.* describes the effects of verotoxin on various cell lines. Mangeney *et al.* use cells obtained from a cell line, and not *primary* cells from a patient. Mangeney *et al.* fails to teach or suggest obtaining *primary* cells from a patient

and treating the primary cells *in vitro* with verotoxin, as claimed by Applicants, let alone the particular claimed variants of the holotoxins.

Thus, the Mangeney *et al.* reference fails to teach or suggest the claimed invention. Therefore, claims 11 and 14-18 are non-obvious in view of Mangeney *et al.* and reconsideration and withdrawal of this rejection under 35 U.S.C. § 103 (a) is requested.

***Rejection of Claims 11, and 14-25 under Judicially Created Doctrine of Obviousness-Type Double Patenting***

Claims 11, and 14-25 were rejected under the judicially created doctrine of obviousness type double patenting over claims 1-9 of U.S. Patent No. 6,228,370 and over claims 1-12 of U.S. Patent No. 5,968,894. The Office Action indicates that timely filed terminal disclaimers in compliance with 37 C.F.R. § 1.312 (c) may be used to overcome a provisional rejection based on a non-statutory double patenting ground provided the conflicting application is shown to be commonly owned with this application. Applicants submit herewith terminal disclaimers in compliance with 37 C.F.R. § 1.312 (c).

Therefore, Applicants respectfully request that this rejection of claims 11 and 14-25 under the judicially created doctrine of obviousness-type double patenting be withdrawn.


**SUMMARY**

Cancellation of and/or amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of the claims is being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application. The amendments made to the claims are not related to any issues of patentability.

In view of the above remarks and amendments, it is believed that this application is in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned or Giulio A. DeConti, Jr., Esq. at (617) 227-7400.

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Respectfully Submitted,  
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